

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 00201-WO10	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, Item 5 below.</small>	
International application No. PCT/DK2004/000573	International filing date (day/month/year) 30/08/2004	(Earliest) Priority Date (day/month/year) 29/08/2003
Applicant LIFECYCLE PHARMA A/S		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK2004/000573

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/436 A61K9/16 A61K9/14 A61P37/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, EMBASE, MEDLINE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/37808 A (LIPOCINE INC) 31 May 2001 (2001-05-31) example 20; claim 1, 5	1-10, 12-16, 21,25, 29,30, 35-40, 42, 47-51,53
X	EP 1 064 942 A (FUJISAWA PHARMACEUTICAL CO) 3 January 2001 (2001-01-03) '0002!-'0004!; example 12, 27, 29 -/-	1-10, 12-16, 18,21, 25, 29-31, 35-42, 47-51,53

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

8 November 2004

30/11/2004

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Authorized officer

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK2004/000573

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>SANO N ET AL: "Oral FK 506 blood levels are elevated in pig short bowel model: Further investigations with co-administration of an intestinal CYP3A4 inhibitor." TRANSPLANTATION PROCEEDINGS, vol. 34, no. 3, May 2002 (2002-05), pages 1050-1051, XP002304068 ISSN: 0041-1345 page 1051, paragraph entitled "Discussion"</p>	1-53
Y	<p>WO 03/004001 A (HOLM JANNIE EGESKOV ; MOELLGAARD BIRGITTE (DK); BUUR ANDERS (DK); HOLM) 16 January 2003 (2003-01-16) cited in the application claims 1-56</p>	1-53
A	<p>HONBO T ET AL: "The oral dosage form of FK-506" TRANSPLANTATION PROCEEDINGS 1987 UNITED STATES, vol. 19, no. 5 SUPPL. 6, 1987, pages 17-22, XP0009024313 ISSN: 0041-1345 table 2; figure 4, 6</p>	1-53
P,Y	<p>NISHI K ET AL: "The expression of intestinal CYP3A4 in the piglet model." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 361-363, XP002304069 ISSN: 0041-1345 page 363, paragraph entitled "Discussion"</p>	1-53
P,Y	<p>NISHI K ET AL: "The colon displays an absorptive capacity of tacrolimus." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 364-366, XP002304070 ISSN: 0041-1345 page 365-366, paragraph entitled "Discussion"</p>	1-53

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2004/000573

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy: Although claim 47 involves a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK2004/000573

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0137808	A	31-05-2001	US 6248363 B1	19-06-2001
			AU 1798101 A	04-06-2001
			CA 2391923 A1	31-05-2001
			EP 1233756 A1	28-08-2002
			JP 2003517470 T	27-05-2003
			WO 0137808 A1	31-05-2001
			US 2003077297 A1	24-04-2003
			US 2003180352 A1	25-09-2003
			US 2003215496 A1	20-11-2003
			US 2003064097 A1	03-04-2003
EP 1064942	A	03-01-2001	AT 269075 T	15-07-2004
			AU 749623 B2	27-06-2002
			AU 2856399 A	18-10-1999
			BR 9909201 A	14-11-2000
			CA 2322516 A1	07-10-1999
			DE 69918074 D1	22-07-2004
			DE 69918074 T2	04-11-2004
			EP 1064942 A1	03-01-2001
			HR 20000707 A1	31-12-2001
			HU 0101237 A2	28-09-2001
			NO 20004773 A	23-11-2000
			NZ 507211 A	25-07-2003
			RU 2214244 C2	20-10-2003
			SK 14392000 A3	12-03-2001
			US 6440458 B1	27-08-2002
			CN 1301157 T	27-06-2001
			EP 1421939 A1	26-05-2004
			ID 27825 A	26-04-2001
			WO 9949863 A1	07-10-1999
			PL 343096 A1	30-07-2001
			TR 200002771 T2	21-02-2001
			TW 570814 B	11-01-2004
			US 2003235614 A1	25-12-2003
			US 2002044967 A1	18-04-2002
			ZA 200004963 A	08-01-2002
WO 03004001	A	16-01-2003	BR 0210867 A	29-06-2004
			CA 2452330 A1	16-01-2003
			WO 03004001 A1	16-01-2003
			EP 1406594 A1	14-04-2004